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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,365	07/19/2005	Lionel Tarassenko	117-537	5031

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EXAMINER	
SORIANO, BOBBY GILES	
ART UNIT	PAPER NUMBER
3769	

MAIL DATE	DELIVERY MODE
10/26/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/528,365	TARASSENKO ET AL.	
	Examiner	Art Unit	
	Bobby Soriano	3769	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 August 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11,14,15,17-21,23-25,27,36 and 37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-11,14,15,17-21,23-25,27,36 and 37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 March 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Examiner acknowledges the amendment filed on August 16, 2010, wherein claims 1-11, 14-15, 17-21, 23-25, 27, and 36-37 are pending.

Response to Arguments

Applicant's arguments filed August 16, 2010 have been fully considered but they are not persuasive.

The Applicant argues that the applied prior art MacCarter fails to disclose trend analysis specific to each patient's characteristics and further alleges that cited paragraphs [0083] – [0091] only suggest comparing data to a group of other patients. The Examiner respectfully disagrees with the Applicant's position. While the patient's data is compared against "models derived from historical profiles" as cited in paragraph [0083], the historical profiles do not merely comprise of profile data from other patients but also of historical data pertaining to the specific patient. This assertion is supported in at least paragraphs [0084] and [0091] and Fig. 15, wherein the system of MacCarter uses graphical analysis techniques and algorithms to observe trending of a patient's own physiological parameters over a period of time such as heart rate variability and other cardiac parameters.

The Applicant further argues that MacCarter does not teach a system with components that require activation and control by the patient, in particular the sensors, software application, and wireless transmitter. The Examiner respectfully disagrees with the Applicant's position. First, the sensors (data gathering devices) are activated by the patient typically without medical supervision as disclosed in paragraph [0032] (although the word "attaching" is used, a data

gathering device would require some form of activation to properly receive and transmit data). Second, the Applicant agreed with the Examiner that an aggregation node is located in the patient's home. Although MacCarter does not expressly disclose control of the aggregation node by the patient, it would be obvious to one of ordinary skill in the art that if an aggregation node is to be located in the patient's home, remote from medical professional care (MacCarter paragraph [0032]), the patient would require some level of control of the aggregation node to configure the system for gathering data and transmitting the data to a remote medical center. This assertion is supported by the fact that MacCarter discloses the aggregation node having a "user-friendly" interface for a patient with limited medical knowledge (MacCarter paragraph [0038]). The assertion by the Applicant that MacCarter does not provide control of the system to the patient would teach away from the rationale for 1) placing the aggregation node in the patient's home without professional supervision and 2) providing a user-interface for a person with limited medical knowledge. The Examiner has included this reasoning in the details of the rejection under 35 U.S.C. 103(a) below. The dependent claims, without there being any arguments directed the merits of the rejection of each dependent claim, are rejected for substantially the same reasoning as previously disclosed.

Note to Applicant Regarding Claim Interpretation

The term "for" followed by an action (i.e. "displaying") in the claims may be interpreted as intended use. Intended use/functional language does not require that reference specifically teach the intended use of the element. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to

patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3, 8-11, 14, 15, 18, 19, 23-25, 27, 36, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over MacCarter US Patent Application 2002/0082867 in view of West US Patent Application 2002/0013517 and further in view of Iliff US Patent Application 2001/0029322.

MacCarter discloses the following of claim 1:

1. A telemedicine system comprising a patient-based physiological data acquisition and transmittal device connectable via a wireless network to transmit physiological data to a remote server, wherein the patient-based physiological data acquisition and transmittal device comprises:

an electronic physiological data acquisition unit which, on being activated by a patient and under the control of the patient measures a physiological parameter of the patient to acquire and output data representing the parameter (Fig. 1 data gathering device 108 as disclosed in paragraphs [0031] and [0032]; paragraph [0032] further states that the data acquiring devices are activated by the patient without professional supervision);

a secure data store (Fig. 1 aggregation node 112 as disclosed in paragraphs [0037] and [0038]);

a wireless transmitter which upon activation by the patient starts a software application to receive the output data from the data acquisition unit, by one of a wireless and wired connection, and to automatically transmit the output data via the wireless network to the remote server (abstract and paragraphs [0037] and [0040]; paragraph [0038] teaches that the aggregation node provides a "patient-friendly interface" to configure the transmission process); and

a display which displays to the patient the data and messages related to the patient's condition (Fig. 3A paragraphs [0038] and [0050] aggregation node 112 comprises a display that displays medical information acquired from the data gathering devices),

wherein the remote computer comprises a data analyzer and an automatic message generator to generate the messages (paragraphs [0054], [0082], and [0091] indicating automatic messaging based on "event thresholds" upon analyzing patient data), and

wherein the data analyzer automatically performs trend analysis of the data with reference to trends tuned to each patient's characteristics (paragraphs [0083] – [0091] indicating trend analysis on acquired physiological data).

MacCarter does not disclose acquiring and storing data when the wireless network is unavailable and automatically transmitting the stored data when a connection to the wireless network is available. However West, a reference in an analogous art, discloses a patient monitoring system comprising of wireless patient monitoring devices with automatic communication restoration capabilities (West paragraphs [0033] and [0097] – [0114]). Therefore it would have been obvious to one of ordinary skill in the art at the time of the

invention to modify the data gathering devices of MacCarter with automatic communication restoration capability as disclosed in West, because West teaches the use of automatic communication restoration increases clinician efficiency by allowing a large number of patients to be monitored without constant intervention by medical personnel to reconfigure the patient monitoring devices after communication dropout occurs (West paragraph [0114]).

MacCarter discloses using trend analysis to automatically generate messages based on acquired physiological data and also assist medical professionals in formulating questions for the patient (MacCarter paragraphs [0039] and [0054]). MacCarter does not disclose automatically creating questions to initiate interaction with the patient and which are furthermore changeable by automatic download from a server in response to changes in the patient's condition. However Iliff, a reference in an analogous art, discloses medical diagnostic network with a script generator to automatically generate patient-specific messages and questions in response to medical data constantly being provided by the patient (paragraphs [0032] and [0127] - [0128]). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the message generator as disclosed in MacCarter to generate questions that change based on the patient's condition as disclosed in Iliff, because Iliff teaches the use of a script generator developed by a consortium of medical experts to generate condition-specific questions can provide patients with more consistent expert and precise advice than a physician unfamiliar with the patient or the patient's condition (Iliff paragraphs [0023] and [0119] – [0120]).

In regards to the newly added claim limitation "wherein the software application is terminatable following receipt of the automated response and the electronic physiological data acquisition unit is deactivatable," MacCarter discloses that the aggregation node can receive

commands from a medical center to modify transmission rates of medical data (MacCarter paragraph [0037]). Although not expressly stated as being capable of deactivating physiological data acquisition processes, it would be obvious to one of ordinary skill in the art that the act of "modifying transmission rates" encompasses also being able to set transmission rates to zero, effectively deactivating physiological monitoring.

Independent claims 36 and 37, without there being any arguments brought up specifically towards the claim language in these claims, are rejected for substantially the same reasoning as independent claim 1, all having been amended to incorporate similar subject matter.

Dependent claims 2-3, 8-11, 14, 15, 18, 19, 23-25, and 27, without there being any arguments directed towards the merits of their rejection, are rejected for substantially the same reasons as disclosed in the previous office action.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bobby Soriano whose telephone number is (571)270-7030. The examiner can normally be reached on Monday thru Friday, 10:30am to 6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Johnson III can be reached on 571-272-4768. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bobby Soriano/
Examiner, Art Unit 3769

/Henry M. Johnson, III/
Supervisory Patent Examiner, Art Unit 3769

October 22, 2010